

REMARKS/ARGUMENTS

Claims 41, 44-51, and 54 are pending in the present Application.

I. Objection to Claim 41

The Office has objected to Claim 41 stating that the recitation in Claim 41 “an individual suffering from fibromyalgia **and** other somatoform disorders” may be interpreted as fibromyalgia **or** other somatoform disorders.

Applicants have amended Claim 41 by deleting the phrase “and other somatoform disorders,” and thus this objection is rendered moot.

II. Objection to Claim 54

The Office has objected to Claim 54 stating that the recitation in Claim 54 “somatoform NOS” should be written such that the meaning contemplated for “NOS” is clearly depicted.

Claim 54 is canceled without prejudice to applicant’s right to file one or more continuing applications directed to the canceled subject matter.

III. Rejection of Claims 41, 44-51 and 54 under 35 U.S.C. 103(a) as unpatentable over Fallon et al.

Claims 41, 44-51 and 54 have been rejected under 35 U.S.C. 103(a) as allegedly being unpatentable over Fallon et al.

Initially, the Office asserted that Fallon teaches the administration of the antidepressant fluoxetine to treat types of hypochondriasis, a somatoform disorder according to DSM-IV.

The Office further states that both reboxetine and fluoxetine are well established in the prior art for use in the treatment of depression and further state that equivalent or similar results are observed in multiple studies comparing the two antidepressants. According to the Office, one skilled in the psychiatry art would have been motivated to administer reboxetine in the treatment of somatoform disorders with a reasonable expectation of therapeutic success. The Office further states that the efficacy in the

treatment of depression closely parallels that of fluoxetine and therefore the Office has maintained rejection of the Claims under 35 U.S.C. 103.

The Fallon document describes the treatment of hypochondriasis with fluoxetine (Prozac®), a well-known selective serotonin reuptake inhibitor. However, the signs and symptoms of hypochondriasis are quite distinct from fibromyalgia: hypochondriacal patients present with a multiplicity of diffuse and vague symptoms which are difficult to characterise, whereas fibromyalgia is specifically defined by the American College of Rheumatology as requiring more than 11 of 18 tender points for the purpose of diagnosis.

Applicants point out that reboxetine acts selectively on the reuptake of noradrenaline, in contrast to fluoxetine which is a serotonergic drug and works by inhibiting the release or affects the action of serotonin. Thus, when comparing these two compounds, the mechanism of action of fluoxetine and the mechanism of action of reboxetine are significantly different. Because of these differences and others which are discussed in the following paragraph, one skilled in the psychiatry art would NOT have been motivated to administer reboxetine in the treatment of somatoform disorders the same reasonable expectation of therapeutic success as with the administration of fluoxetine, nor with the same expectation of side effects or benefits of therapy when reboxetine is used rather than fluoxetine.

Furthermore, the known non-depression indications of NRIs and SSRIs are quite different (in particular, SSRIs are generally considered to be inactive in pain relief); in particular, there is no common "class effect" in the treatment of somatoform disorders shared by all antidepressants.

Therefore, the skilled psychiatrist would not, on reading the Fallon document, assume that even an SSRI, much less a selective NRI such as racemic reboxetine, would be suitable to treat a different somatoform disorder such as fibromyalgia. The Fallon document thereby provides no motivation to the skilled psychiatrist to try, with an expectation of success, using racemic reboxetine to treat fibromyalgia.

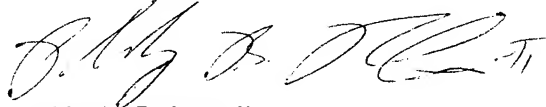
IV. Request for Continued Examination (RCE)

The present Office Action has been made Final. The Applicants have included an RCE in the present Office Action response.

V. Conclusion

If the Examiner believes a telephonic interview with Applicant's representative would aid in the prosecution of this application, the Examiner is cordially invited to contact Applicant's representative at the below listed number.

Respectfully submitted,

A handwritten signature in black ink, appearing to read "Philip B. Polster II". The signature is fluid and cursive, with the first name "Philip" being the most prominent part.

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